# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

# FORM 8-K

## CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): November 07, 2024**

# Cardiff Oncology, Inc.

**(Exact name of Registrant as Specified in Its Charter)**

| **Delaware** | **001-35558** | **27-2004382** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |
| **11055 Flintkote Avenue San Diego, California** | | **92121** |
| **(Address of Principal Executive Offices)** | | **(Zip Code)** |

**Registrant's Telephone Number, Including Area Code: (858) 952-7570**

**(Former Name or Former Address, if Changed Since Last Report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Securities registered pursuant to Section 12(b) of the Act:**

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock | CRDF | The Nasdaq Stock Market LLC |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 2.02 Results of Operations and Financial Condition.**

On November 7, 2024, Cardiff Oncology, Inc. issued a press release announcing company highlights and financial results for the second quarter ended September 30, 2024. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

99.1 Press Release of Cardiff Oncology, Inc. dated November 7, 2024

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CARDIFF ONCOLOGY, INC.

Date: November 7, 2024

By: /s/ Mark Erlander
Mark Erlander

Chief Executive Officer

# Cardiff Oncology Reports Third Quarter 2024 Results and Provides Business Update

*- Published positive Phase 2 trial results of onvansertib in combination with FOLFIRI and bev in second-line KRAS mutant mCRC in the peer-reviewed Journal of Clinical Oncology -*

*- Initial data readout from first-line RAS-mutated mCRC randomized CRDF-004 trial expected by the end of 2024-*

*- Projected runway with current cash resources into Q1 2026 -*

**SAN DIEGO, November 7, 2024** -- Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company leveraging PLK1 inhibition to develop novel therapies across a range of cancers, today announced financial results and recent highlights for the third quarter ended September 30, 2024.

“This quarter has been exciting as our Phase 2 clinical trial in second-line KRAS-mutant mCRC was published in one of the most esteemed medical journals in the field of oncology, Journal of Clinical Oncology. Our findings demonstrated that onvansertib combined with FOLFIRI/bev was well-tolerated, and revealed a 7.7x greater clinical benefit in bev naïve patients compared to patients who were previously treated with bev,” said Mark Erlander, Ph.D., Chief Executive Officer of Cardiff Oncology. “We believe the results of our JCO publication validate our ongoing CRDF-004 trial evaluating onvansertib + chemo for the treatment of mCRC in the first-line setting, where all patients are bev naïve. Furthermore, we are pleased with the progress we have made in the trial as we leverage Pfizer’s resources and capabilities, and are grateful for the commitment from the patients and investigators at our trial sites across the U.S. As of today, the trial continues to generate patient data that will allow us to provide an initial data release by the end of the year. Overall, we are optimistic about onvansertib’s potential to become a meaningful treatment option for the 50,000 new patients diagnosed with RAS-mutated mCRC in the U.S. every year who have not had access to any new treatment options in several decades.”

**Upcoming expected milestones**

- First-line RAS-mutated metastatic colorectal cancer (mCRC) randomized initial data readout from the CRDF-004 trial expected by end of 2024

**Company highlights for the quarter ended September 30, 2024 and subsequent weeks include:**

- **Published clinical data of the combination of onvansertib with FOLFIRI and bev in second-line KRAS mutant mCRC in the peer-reviewed *Journal of Clinical Oncology*, the flagship publication of the American Society of Clinical Oncology (ASCO)**
    - Phase 2 clinical trial treating patients with KRAS-mutant mCRC (NCT03829410) demonstrated that onvansertib combined with FOLFIRI and bev was well-tolerated, and exhibited clinical activity in the second-line setting.
    - A post hoc analysis revealed a greater clinical benefit in bev naïve patients, who demonstrated an ORR of 77% and mPFS of 14.9 months compared to an ORR of 10% and mPFS of 6.6 months in those previously exposed to bev.

- **Published promising preclinical data demonstrating the combination of onvansertib and alpelisib in PIK3CA-mutated HR-positive breast cancer resistant to palbociclib and endocrine therapy in the peer-reviewed journal, *Cancers***
    - The combination of onvansertib and alpelisib synergistically inhibited cell viability, suppressed PI3K signaling, and induced G2/M arrest and apoptosis in PI3K-activated cell lines.
    - The combination demonstrated superior anti-tumor activity compared to the single agents in three PDX models.
    - Pharmacodynamic studies confirmed inhibition of both PLK1 and PI3K activity and pronounced apoptosis in the combination-treated tumors.
    - The findings support that targeting PLK1 and PI3Kα with onvansertib and alpelisib, respectively, may be a promising strategy for patients with PIK3CA-mutant HR+ breast cancer failing ET + CDK4/6i therapies and warrant clinical evaluation.

**Third Quarter 2024 Financial Results**

*Liquidity, cash burn, and cash runway*

As of September 30, 2024, Cardiff Oncology had approximately $57.7 million in cash, cash equivalents, and short-term investments.

Net cash used in operating activities for the third quarter of 2024 was approximately $10.5 million, an increase of approximately $2.5 million from $8.0 million for the same period in 2023.

Based on its current expectations and projections, the Company believes its current cash resources are sufficient to fund its operations into Q1 2026.

*Operating results*

Total operating expenses were approximately $12.8 million for the three months ended September 30, 2024, an increase of $1.8 million from $11.0 million for the same period in 2023. The increase in operating expenses was primarily due to clinical programs and outside service costs related to the development of our lead drug candidate, onvansertib.

**About Cardiff Oncology, Inc.**

Cardiff Oncology is a clinical-stage biotechnology company leveraging PLK1 inhibition, a well-validated oncology drug target, to develop novel therapies across a range of cancers. The Company's lead asset is onvansertib, a PLK1 inhibitor being evaluated in combination with standard of care (SoC) therapeutics in clinical programs targeting indications such as RAS-mutated metastatic colorectal cancer (mCRC), as well as in ongoing and planned investigator-initiated trials in metastatic pancreatic ductal adenocarcinoma (mPDAC), small cell lung cancer (SCLC) and triple negative breast cancer (TNBC). These programs and the Company's broader development strategy are designed to target tumor vulnerabilities in order to overcome treatment resistance and deliver superior clinical benefit compared to SoC alone. For more information, please visit https://www.cardiffoncology.com.

**Forward-Looking Statements**

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified using words such as "anticipate," "believe," "forecast," "estimated" and "intend" or other similar terms or expressions that concern Cardiff Oncology's expectations, strategy, plans or intentions. These forward-looking statements are based on Cardiff Oncology's current expectations and actual results could differ materially. There are several factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results; our clinical trials may be suspended or discontinued due to unexpected side effects or other safety risks that could preclude approval of our product candidate; results of preclinical studies or clinical trials for our product candidate could be unfavorable or delayed; our need for additional financing; risks related to business interruptions, including the outbreak of an epidemic or pandemic such as the COVID-19 coronavirus and cyber-attacks on our information technology infrastructure, which could seriously harm our financial condition and increase our costs and expenses; uncertainties of government or third party payer reimbursement; dependence on key personnel; limited experience in marketing and sales; substantial competition; uncertainties of patent protection and litigation; dependence upon third parties; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. There are no guarantees that our product candidate will be utilized or prove to be commercially successful. Additionally, there are no guarantees that future clinical trials will be completed or successful or that our product candidate will receive regulatory approval for any indication or prove to be commercially successful. Investors should read the risk factors set forth in Cardiff Oncology's Form 10-K for the year ended December 31, 2023, and other periodic reports filed with the Securities and Exchange Commission. While the list of factors presented here is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof, and Cardiff Oncology does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

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**Cardiff Oncology, Inc.**
**Condensed Statements of Operations**
**(in thousands, except for per share amounts)**
**(unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Royalty revenues | $ 165 | $ 141 | $ 532 | $ 332 |
| Costs and expenses: | | | | |
| Research and development | 9,640 | 8,022 | 27,140 | 25,094 |
| Selling, general and administrative | 3,126 | 2,939 | 9,471 | 10,318 |
| Total operating expenses | 12,766 | 10,961 | 36,611 | 35,412 |
| Loss from operations | (12,601) | (10,820) | (36,079) | (35,080) |
| Other income (expense), net: | | | | |
| Interest income, net | 741 | 1,068 | 2,472 | 3,061 |
| Other income (expense), net | 5 | 21 | (37) | (85) |
| Total other income, net | 746 | 1,089 | 2,435 | 2,976 |
| Net loss | (11,855) | (9,731) | (33,644) | (32,104) |
| Preferred stock dividend | (6) | (6) | (18) | (18) |
| Net loss attributable to common stockholders | $ (11,861) | $ (9,737) | $ (33,662) | $ (32,122) |
| Net loss per common share — basic and diluted | $ (0.25) | $ (0.22) | $ (0.74) | $ (0.72) |
| Weighted-average shares outstanding — basic and diluted | 46,865 | 44,677 | 45,461 | 44,677 |

**Cardiff Oncology, Inc.**
**Condensed Balance Sheets**
**(in thousands)**
**(unaudited)**

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | $ 13,038 | $ 21,655 |
| Short-term investments | 44,629 | 53,168 |
| Accounts receivable and unbilled receivable | 618 | 288 |
| Prepaid expenses and other current assets | 1,047 | 2,301 |
| Total current assets | 59,332 | 77,412 |
| Property and equipment, net | 993 | 1,238 |
| Operating lease right-of-use assets | 1,304 | 1,708 |
| Other assets | 1,267 | 1,279 |
| Total Assets | $ 62,896 | $ 81,637 |
| | | |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | $ 4,643 | $ 1,966 |
| Accrued liabilities | 7,175 | 7,783 |
| Operating lease liabilities | 707 | 691 |
| Total current liabilities | 12,525 | 10,440 |
| Operating lease liabilities, net of current portion | 979 | 1,458 |
| Total Liabilities | 13,504 | 11,898 |
| | | |
| Stockholders' equity | 49,392 | 69,739 |
| Total liabilities and stockholders' equity | $ 62,896 | $ 81,637 |

**Cardiff Oncology, Inc.**
**Condensed Statements of Cash Flows**
**(in thousands)**
**(unaudited)**

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2024** | **2023** |
| **Operating activities** | | |
| Net loss | $ (33,644) | $ (32,104) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 308 | 295 |
| Stock-based compensation expense | 3,556 | 3,600 |
| Accretion of discounts on short-term investments, net | (440) | (716) |
| Changes in operating assets and liabilities | 2,794 | 5,177 |
| Net cash used in operating activities | (27,426) | (23,748) |
| | | |
| **Investing activities** | | |
| Capital expenditures | (80) | (574) |
| Net purchases, maturities and sales of short-term investments | 9,297 | 23,208 |
| Net cash provided by investing activities | 9,217 | 22,634 |
| | | |
| **Financing activities** | | |
| Proceeds from sales of common stock, net of expenses | 9,232 | — |
| Proceeds from exercise of options | 360 | — |
| Net cash provided by financing activities | 9,592 | — |
| Net change in cash and cash equivalents | (8,617) | (1,114) |
| Cash and cash equivalents—Beginning of period | 21,655 | 16,347 |
| Cash and cash equivalents—End of period | $ 13,038 | $ 15,233 |